



European Commission
Enterprise & Industry Directorate General

NEW OSH ERA
Forum on new and emerging OSH risks
“Towards a sustainable working life”

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Regulatory developments with respect to nanomaterials

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Legislation

**Instruments of implementation,
RA, testing, guidance,
standards.....**

Implementation

Research and Development



REACH

Environment

Regulation

Implementing
regulation

Standards

Guidance

Science,
literature

Pharmaceuticals Food

Cosmetics Biocides

Worker

Sports Equipment

Protection

Plant protection

Consumer goods,etc



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- No legal void; in principle covered, but change of legislation may be required and will be proposed as necessary
- Implementation remains a challenge, as instruments of implementation are still lacking, although they are gradually being built up
- Lack of knowledge impedes us for the time being to elaborate general guidance, measures, standards, methods
- Therefore, implementation on a case by case basis, with major role for enforcement in order to respect principle of “no data – no market”



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National initiatives

- Various Member States have launched national programmes
- Draft Regulation to be notified to the European Commission and Member States
- Need to maintain a consistent and coherent legal framework in Europe, respecting the unity of the market and effectiveness of measures
- In certain policy areas, EU legislation lays down minimum requirements and Member States can take more stringent measures



Stakeholders

- Not always consistent views between different groups of stakeholders
- Genuine concern to take concerns and suggestions into consideration
- Present in all Commission Working Groups on regulation
- Various platforms for dialogue, e.g. Safety for Success



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European Economic and Social Committee

- Highlights the need for an “integrated regulatory frame of reference {...}, as well as a system of governance, with the aim of providing clear and reliable answers to the emerging needs, particularly as regards common classification methods, metrology and testing, validation of existing protocols, new protocols, and pre-normative and co-normative research”
- Asks special attention for the role of standardisation

provisions therein,
with the Commission's conclusions that

 a) current legislation covers in principle the relevant risks relating to nanomaterials, and that

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b) the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation,

when, due to the lack of appropriate data and methods to assess the risks relating to nanomaterials, it is effectively unable to address their risks”



Hence, European Parliament asks to

- address explicitly nanomaterials in the scope of regulation on chemicals, food, and relevant worker protection and environmental protection
- review legislation and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed
- evaluate the need to review REACH, waste legislation, air and water legislation, worker protection legislation, on particular aspects



On worker protection, the European Parliament

Calls specifically on the Commission to evaluate the need to review legislation concerning inter alia:

- The use of nanomaterials only in closed systems or in other ways that exclude exposure of workers as long as it is not possible to reliably detect and control exposure
- A clear assignment of liability to producers and employers arising from the use of nanomaterials
- whether all exposure routes (inhalation, dermal and other) are addressed.



European Parliament also request

- a comprehensive, science based definition, harmonised at the global level
- an inventory of different types and uses of nanomaterials on the market, and a report on their safety
- better information to consumers, by mandatory indicating “nano ingredients” in labelling, regardless of risks



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European Parliament confirms that

- nanomaterials should be covered by a multi-faceted, differentiated and adaptive body of law { }, while avoiding systematic recourse to general moratoria or undifferentiated treatment of different applications of nanomaterials
- the almost infinite application of nanotechnologies to such diverse sectors as electronics, textiles, biomedical, personal care products, cleaning products, food or energy makes it impossible to introduce a single regulatory framework at Community level



Next steps on regulation

- An ongoing process on development of instruments of implementation
- A commitment to propose legislative change each time there is a need
- An explicit position on issues raised by the European Parliament, each time the Commission proposes a recast or new legislation
- A position to be taken on labelling on a case by case basis
- Continuing work on definitions and terminology, bridging the knowledge gap, in cooperation with international partners
- An review of legislation, including instruments of implementation, in 2011
- An inventory of uses and types of nanos, including safety aspects, 2011
- Particular attention to be given to REACH and its implementation, including first phase of registrations (2010)



Next steps on worker protection

- Framework Directive (89/391/EEC) and the chemical agents Directive (98/24/EC), cover in principle the risks related to nanomaterials

Based on scientific and technical data on risk assessment and risk management , issue can be further discussed in the Advisory Committee on Safety and health at Work and the SCOEL

- Evaluation of risks associated with hazardous chemicals and fixing priorities in the light of seriousness of risks and resources available. No scientific evidence that risks to workers health caused by nano's prevail to risks caused by carcinogenic and mutagenic substances.
- Social partners and representatives of the EU MS in the Advisory Committee can take a different view and propose to discuss priorities



Conclusions

- Critical years ahead of us
- Important milestones next few years
- Challenges to be covered in new Commission Action Plan on Nanomaterials and Nano technologies